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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,586

12/13/2006

Jean Krutmann

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EXAMINER

KAROL, JODY LYNN

ART UNIT

PAPER NUMBER

1627

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,586	<b>Applicant(s)</b> KRUTMANN, JEAN	
	<b>Examiner</b> Jody L. Karol	<b>Art Unit</b> 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8/5/2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Amendment/Remarks filed 8/5/2009.

Claims 11 and 14-15 have been amended. Claims 1-10 and 12-13 are cancelled.

Claims 11 and 14-19 are pending and are currently under consideration.

### **WITHDRAWN REJECTIONS**

1. In view of Applicant's amendment to claim 14, the objection to claim 14 is herein withdrawn.

2. In view of Applicant's amendment to claim 11 and 15, the rejection of claims 11 and 14-19 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being indefinite, is herein withdrawn.

3. Applicant's arguments with respect to the rejection of claims 11 and 14-19 under 35 U.S.C. 103(a) as being unpatentable over Buchholz et al. (US 2004/0053860 A1) have been fully considered and are persuasive. Thus, said rejection is herein withdrawn.

### ***Response to Arguments***

4. Applicant's arguments filed 8/5/2009 have been fully considered and are persuasive. Therefor, the rejection has been withdrawn in favor of the new ground(s) of rejection presented below.

**NEW REJECTIONS**

5. After further consideration, the following rejections have been newly added:

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 11, 14, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motitschke et al. (US 6,060,071) in view of Hanifin et al. ("Effects of a Low-potency Corticosteroid Lotion Plus a Moisturizing Regimen in the Treatment of Atopic Dermatitis," *Current Therapeutic Research*, Vol. 59, No. 4, April 1998, pgs 227-233).

The instant claims are directed to a method of treatment of neurodermatitis comprising topical application of a dermatological preparation comprising an osmolyte or a pharmacologically compatible salt thereof to a patient in need of such treatment, wherein the osmolyte is ectoine or hydroxyectoine or a pharmacologically compatible salt thereof.

It is noted that on page 2 of the instant specification, neurodermatitis is also termed endogenous eczema or atopic dermatitis.

Motitschke et al. teach cosmetic preparations comprising (S)-1,4,5,6-tetrahydro-2-methyl-4-pyrimidinecarboxylic acid (ectoin) and/or (S,S) -1,4,5,6-tetrahydro-5hydroxy-2-methyl-4-pyrimidinecarboxylic acid (hydroxyectoin) for the care of dry and/or irritated skin, in particular for increasing and/or stabilizing the moisture content of skin (see abstract; column 1, line 39 to column 2, line 41; column 6, lines 13-17). The compounds (i.e. ectoin and/or hydroxyectoin) are formulated with auxiliaries and/or carrier substances to give a suitable formulation, wherein examples of use forms include ointments, creams, lotions, sprays, etc. as claimed in instant claim 14 (see column 5, lines 1-13). Motitschke et al. also teach other active substances may be

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added to the product as claimed in the instant claim 17 (see column 5, lines 13-16).

Motitschke et al. further teach that in patients suffering from atopy, the symptoms of dry skin or observed irrespective of age, and that the skin condition can be prevented or counteracted by using suitable moisturizing preparation (see column 1, lines 15-30).

Motitschke et al. do not explicitly teach treating neurodermatitis (atopic dermatitis) using the ectoin and/hydroxyectoin compositions.

Hanifin et al. teach that treatment of atopic dermatitis is directed towards reducing inflammation and using moisturizers to maintain a flexible, hydrated stratum corneum (see page 228). Hanifin et al. further teach that the addition of a moisturizer to a low-potency topical corticosteroid lotion (i.e. desonide lotion 0.05%, an antiphlogistic and glucocorticoid as claimed in the instant claims 18-19) in separate regimens was effective in treating the signs and symptoms of mild-to-moderate atopic dermatitis (see abstract). The addition of the moisturizing cream produced significant reduction of up to 23% in the clinical signs and symptoms of atopic dermatitis, which support and overwhelming patient preference for the desonide/moisturizer combination over desonide alone (see pages 231-232, bridging paragraph; page 232 last paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat atopic dermatitis (neurodermatitis) using as moisturizer as taught by Hanifin et al., wherein the moisturizer is the ectoin/hydroxyectoin formulation as taught by Motitschke et al. One of ordinary skill in the art would have been motivated to use the ectoin/hydroxyectoin formulation to treat atopic dermatitis because ectoin/hydroxyectoin formulations improve and stabilize the hydration of the skin. One

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of ordinary skill in the art would have had a reasonable expectation of success in using the ectoin/hydroxyectoin formulations to treat atopic dermatitis (neurodermatitis) because Motitschke et al. teach that dry skin conditions can be counteracted with said moisturizing preparations, and mention that patients suffering from atopy have dry skin conditions irrespective of age. Further, Hanifin et al. explicitly teach the use of a moisturizer in the treatment of atopic dermatitis.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

8. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motitschke et al. (US 6,060,071) in view of Hanifin et al. ("Effects of a Low-potency Corticosteroid Lotion Plus a Moisturizing Regimen in the Treatment of Atopic Dermatitis," *Current Therapeutic Research*, Vol. 59, No. 4, April 1998, pgs 227-233). as applied to claims 11, 14, and 17-19 above, and further in view of Touitou et al. ("Liposomes as Carriers for Topical and Transdermal Delivery," *Pharmaceutical Sciences*, Vol. 83, No. 9, Sept. 1994, pgs 1189-1203).

Motitschke et al. and Hanifin et al. are described *supra* as applied to claims 11, 14, and 17-19.

Motitschke et al. and Hanifin et al. do not teach the dermatological preparation comprises liposomes containing the osmolyte (i.e. ectoin, hydroxyectoin, or pharmaceutically acceptable salts thereof).

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Touitou et al. teach the advantages of using liposomes as drug carriers for topical delivery, wherein the use of liposomes allows for increased accumulation of the drug in the skin (see abstract; pages 1189-1192, column 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the liposomes taught by Touitou et al. as carriers for the ectoin and/or hydroxyectoin in the method of treating atopic dermatitis obvious over Motitschke et al. in view Hanifin et al. One of ordinary skill in the art would have been motivated to employ liposomes as carriers for the ectoin and/or hydroxyectoin in order to provide the advantages of topical delivery of drugs associated with liposomes, such as the accumulation of the drug in the skin. One of ordinary skill in the art would have had a reasonable expectation of success in employing the liposomes as carriers for ectoin and/or hydroxyectoin because the method of treating atopic dermatitis obvious over Motitschke et al. in view Hanifin et al. employs a topical composition comprising ectoin and/or hydroxyectoin and Touitou et al. teach the liposomes are drug carriers for topical compositions.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

### **Conclusion**

No claims are allowed.



***Correspondence***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1627

/Yong S. Chong/  
Primary Examiner, Art Unit 1627